

Ralph Zipper, M.D.

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IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY
TRIAL DIVISION

Plaintiff,

vs.

ETHICON, INC., et al.,

Defendants,

— — —

SEPTEMBER 26, 2015

— — —

Deposition of RALPH ZIPPER, MD, held at Zipper Urogynecology Associates, 200 South Harbor City Boulevard, Suite 401, Melbourne, Florida, commencing at 9:52 a.m., on the above date, before Joan L. Pitt, Registered Merit Reporter, Certified Realtime Reporter, and Florida Professional Reporter.

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1 **Q.** And are those primarily polypropylene
2 midurethral slings?

3 **A.** They are almost exclusively retropubic
4 polypropylene slings. I have not placed any material
5 through the transobturator foramen in quite some time.

6 **Q.** And what type of -- what brand of midurethral
7 sling do you currently use?

8 **A.** The most common one is the AMS SPARC sling.

9 **Q.** AMS what?

10 **A.** SPARC, S-P-A-R-C.

11 **Q.** And I assume that you've done thousands of SUI
12 procedures using midurethral slings; is that true?

13 MR. THORNBURGH: Objection. Over what time
14 period?

15 MR. MORIARTY: In his career.

16 **A.** Yes.

17 **Q.** So this paragraph on the beginning of page 3 of
18 your report says, "I have worked closely with engineers
19 to develop devices, including slings."

20 Was that with the medical device manufacturers,
21 Bard, or AMS, or another?

22 **A.** I actually worked with an engineer employed by
23 myself to improve and develop sling and pelvic organ
24 prolapse technology in a deal with Mpathy to take their

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1 low efficacy mini sling and sheet mesh to the US market
2 in a diversified product line with improved efficacy,
3 create sales, and get an exit.

4 I spent approximately one and a half years of
5 my life and thousands of hours working on the
6 engineering and deployment of those product lines, and
7 those modifications were commercialized and subsequently
8 sold to Coloplast, and the details of those
9 interactions, which involve thousands of pages, may be
10 or may not be confidential following the settlement that
11 took place.

12 **Q.** That's what that lawsuit was about, basically;
13 right?

14 **A.** Yes.

15 **Q.** In Mrs. Hammons -- we can talk more about this
16 later.

17 What is the basis for your opinion that she
18 suffered some clinical signs and symptoms secondary to
19 contraction of mesh?

20 **A.** Signs and symptoms of contraction. Signs of
21 contraction include failure of the device to perform
22 according to its implication, which is long-acting,
23 long-term stabilization of pelvic supporting structures.
24 I believe it's -- the wording is quite similar in the

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1 atypical familiarity with the mesh manufacturing process
2 and the physical properties of mesh.

3 However, I do not represent myself as an expert
4 in materials science.

5 Q. Okay. The work that you just described, is
6 that something different than -- let me withdraw that.

7 When I asked you the initial question about do
8 you have training beyond what a doctor or
9 urogynecologist has, you said something about "from my
10 experience or my research," and then I just -- and then
11 you just explained to me some experience that you've
12 had. Okay?

13 Is the research that you've done separate from
14 what you've just explained to us about your work with
15 that company?

16 A. Yes, it's in addition to that. I would sit
17 down with manufacturers, I would get to talk to
18 engineers and hear things about the manufacturing
19 process and mesh properties that a urogynecologist or
20 gynecologist would not hear, and then I would go home
21 and dig deeper and do my own research.

22 That's why many of these articles on the
23 reliance list I was familiar with long before I was
24 involved in this litigation.

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1 But I did not obtain an engineering degree in
2 materials science or attend classes in materials science
3 when in training.

4 **Q.** Okay. When was this work that you're
5 describing in the development of those products?

6 **A.** I can't recall. Probably starting in or about
7 2006 going through probably about 2009 or 2010. This is
8 just a guess.

9 THE WITNESS: Dinner break?

10 MR. THORNBURGH: I've got some food in my
11 duffle bag.

12 THE WITNESS: Will you share?

13 (Discussion off the record.)

14 THE WITNESS: Mr. Moriarty, while you're doing
15 your review, I think I'll hit the head, if that's
16 okay.

17 MR. MORIARTY: Go ahead.

18 (Recess from 4:45 p.m. until 4:52 p.m.)

19 (Zipper Exhibit No. 16 was marked for
20 identification.)

21 BY MR. MORIARTY:

22 **Q.** Doctor, I'm going to hand you what I've marked
23 as Exhibit 16. It's an article that's on your reliance
24 list and you refer to it at page 19 of your report in

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1 **A.** I only know that I opined. That's it.

2 Q. Okay. Do you hold yourself out in any context
3 outside litigation in being an expert in FDA regulations
4 regarding labeling?

5 MR. THORNBURGH: Objection.

6 **A.** It's an interesting question without an easy
7 answer. Most labeling experts sit on the side -- have
8 experience on the side of the FDA, have worked in the
9 FDA, often in the ODE or other departments in the FDA,
10 and then go out into the private sector.

11 My experience is looking at it from the other
12 end in product development and working through the
13 regulations as an executive in the device company. And
14 so where I do not hold myself out as a regulatory
15 expert, I do hold myself out as having an expert level
16 of knowledge on the corporate side of helping to
17 determine regulatory pathways and pursue those
18 regulatory pathways.

19 Q. Handing you Exhibit 6B.

20 MR. MORIARTY: Dan, I think I gave you the
21 whole pack at one time. Let me know if I didn't.

22 Q. Is that a printout of a section of your website
23 entitled "Dr. Zipper Explains Urgency Incontinence"?

24 **A.** It may be.

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1 **Q.** How do you know you are?

2 **A.** It has become the industry standard for clients
3 such as yours, Ethicon, to determine who the national
4 thought leaders are, and device companies have qualified
5 me as a national thought leader.

6 **Q.** Okay. Did you ever do any preceptor work for
7 Ethicon?

8 **A.** I do not recall.

9 **Q.** Have you ever performed studies on contraction
10 or shrinkage rates of mesh?

11 **A.** I have not.

12 **Q.** Have you ever performed a study on degradation
13 of mesh?

14 **A.** I have not.

15 **Q.** Have you ever performed a study on the
16 difference between laser or mechanically cut mesh?

17 **A.** I have not.

18 **Q.** Have you ever prepared a 510(k) application?
19 MR. THORNBURGH: Asked and answered.

20 **A.** I've assisted, but I have not been the sole
21 preparer of a 510(k) application.

22 **Q.** Was that for one of the products intended to be
23 manufactured and sold by one of your companies?

24 **A.** Yes.

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C E R T I F I C A T E

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3 I, JOAN L. PITTS, Registered Merit Reporter,
4 Certified Realtime Reporter, and Florida Professional
5 Reporter, do hereby certify that, pursuant to notice,
6 the deposition of RALPH ZIPPER, MD, was duly taken on
7 SEPTEMBER 26, 2015 at 9:52 a.m., before me.

8 The said RALPH ZIPPER, MD, was duly sworn by me
9 according to law to tell the truth, the whole truth, and
10 nothing but the truth, and thereupon did testify as set
11 forth in the above transcript of testimony. The
12 testimony was taken down stenographically by me. I do
13 further certify that the above deposition is full,
14 complete, and a true record of all the testimony given
15 by the said witness.

16

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JOAN L. PITTS, RMR, CRR, FPR

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20 (The foregoing certification of this transcript
21 does not apply to any reproduction of the same by any
22 means, unless under the direct control and/or
23 supervision of the certifying reporter.)

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